**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| IN RE APPLIED THERAPEUTICS SECURITIES LITIGATION | Case No. 1:24-CV-09715 (DLC) (VF)<br><br>**ECF Case** |

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT SHOSHANA SHENDELMAN'S MOTION TO DISMISS THE CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**

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## TABLE OF DEFINED TERMS

| Abbreviation | Definition |
|---|---|
| Adult Study | The ACTION-Galactosemia Phase 1/2 Study, Applied's first clinical trial targeting galactosemia, initiated in June 2019. Compl. ¶48. |
| Applied | Applied Therapeutics, Inc. |
| Class Period | The putative Class Period between January 3, 2024 and December 2, 2024, inclusive. *Id.* ¶1. |
| Complaint | The Consolidated Amended Class Action Complaint filed on May 2, 2025. ECF No. 72. |
| CRL | The Complete Response Letter received by Applied and Dr. Shendelman on November 27, 2024. *Id.* ¶272. |
| Data Deletion | A vendor's deletion, on March 27, 2024, of electronic data for subjects in the Pediatric Study. *Id.* ¶10. |
| Dosing Errors | Labeling error causing 19 subjects enrolled in the Pediatric Study to receive approximately 80% of the intended dose of govorestat between March and June 2021. *Id.* ¶3. |
| FDA | The U.S. Food and Drug Administration. |
| Form 483 | The Form 483 given to Dr. Shendelman on May 3, 2024. *Id.* ¶12. |
| Inspection | The FDA's inspection, between April 29, 2024 and May 3, 2024 conducted as part of the FDA's Bioresearch Monitoring Program. *Id.* ¶¶130 |
| Late-Cycle Meeting | Applied's late-cycle review meeting with the FDA completed by September 18, 2024. *Id* ¶237. |
| Mid-Cycle Meeting | Applied's mid-cycle review meeting with the FDA completed late Spring 2024. *Id.* ¶230. |
| NDA | The New Drug Application for govorestat to treat galactosemia submitted by Applied in December 2023 and accepted by the FDA in February 2024. *Id*. ¶¶2, 62, 85. |
| PDUFA | The Prescription Drug User Fee Act. |
| Pediatric Study | The ACTION-Galactosemia Kids Study for govorestat initiated June 2020, also referred to as ACTION-Kids or AT-007-1002. *Id*. ¶¶3, 54. |
| Pediatric Study Results | Results of the Pediatric Study. *See* Evan Bailey et. al., *Results of the ACTION-Galactosemia Kids Study to Evaluate the* |

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| | *Effects of Govorestat in Pediatric Patients with Classic Galactosemia*, JOURNAL OF CLINICAL PHARMACOLOGY (2024). |
| Plaintiff | Martin Dietrich, Lead Plaintiff. |
| PSLRA | Private Securities Litigation Reform Act of 1995. |
| Q-Global | A Web-based administration system used by Applied to capture certain electronic clinical outcome assessments. *Id*. ¶128. |

## PRELIMINARY STATEMENT

The law does not require executives to be clairvoyant, nor does it require them to assume the worst. Particularly in the context of the development and approval of a new drug, courts recognize the complexity and unpredictability of the regulatory process and decline to impose securities liability except where executives ***know***, and fail to disclose, that existing issues will ***necessarily prevent*** FDA approval. The Complaint fails to allege such particularized facts and should be dismissed.

Shoshana Shendelman is a Ph.D. scientist whose life's work led her to found Applied,[1] a clinical-stage biopharmaceutical company focused on combatting untreated rare diseases. Specifically, Dr. Shendelman led the development of govorestat, a first-of-its-kind drug to treat galactosemia, a rare and debilitating neurological disorder primarily affecting children.

In December 2023, after years of clinical research, Applied submitted a New Drug Application for govorestat, which the FDA accepted and granted Priority Review in February 2024. Dr. Shendelman and her colleagues communicated regularly with the FDA as Applied moved through important milestones, completing an FDA inspection in May 2024, and holding Mid-Cycle and Late-Cycle Meetings with the FDA. At each step, the FDA could have issued a Complete Response Letter, the FDA's mechanism for rejecting an NDA. Each time the FDA did not issue a CRL, but instead set the date for the next milestone, Applied moved closer to possible approval and commercialization of govorestat. And while the FDA identified issues with the application, including a dosing error during the clinical phase and a vendor's deletion of source data prior to an FDA inspection, the FDA never indicated that these issues warranted a CRL. So

[1] Capitalized terms not defined in the Table of Defined Terms shall have the same meanings ascribed to them in the Complaint.

as Applied moved closer to possible approval, Dr. Shendelman shared that progress and forward movement with the investing public—all the while noting, of course, that there were still risks govorestat would not be approved.

In late November 2024, however, the FDA issued a CRL and a Warning Letter, which pointed to the dosing errors and data deletion. In the days that followed, Applied stockholders—including Dr. Shendelman, who owned more than seven million shares—saw Applied's stock price plummet.

Plaintiff's securities fraud claim amounts to an argument that Dr. Shendelman and Applied should have known govorestat would not be approved but misrepresented the facts of the NDA review and failed to disclose issues identified by the FDA. Plaintiff further alleges that Dr. Shendelman had a motive to commit fraud, because she wanted to keep Applied's stock price high, including so she could execute sales of Applied stock throughout the Class Period. This theory fails under settled law because (i) courts recognize that all corporate leaders want to see their companies succeed, and (ii) the modest size of Dr. Shendelman's trades—two of which were non-discretionary trades made for tax purposes, and none representing more than 10% of her then-current holdings—cannot support an inference of scienter. Alternatively, Plaintiff alleges that circumstantial evidence shows that Dr. Shendelman knew or should have known that the FDA would not approve govorestat. But Plaintiff's only support for this theory is conjecture, hindsight, and allegations that Dr. Shendelman was unduly optimistic about the possibility of approval, none of which satisfies the rigorous requirements for pleading scienter under the Federal securities laws. Rather than supporting an inference of scienter, the facts alleged are far more consistent with an inference that Dr. Shendelman honestly believed govorestat ***could*** be approved.

Moreover, numerous alleged misstatements in the Complaint are inactionable as a matter of law. Statements regarding the outlook and progress of drug development and interactions with the FDA are quintessential puffery and expressions of corporate optimism that cannot give rise to securities fraud under settled precedent. Nor can Plaintiff base a Section 10(b) claim on accurate statements of fact regarding the progress of the FDA review.

At bottom, a failure to accurately predict the future is not fraud, and the Court should dismiss the Complaint.

## FACTUAL BACKGROUND[2]

### A. The Development of Govorestat

Dr. Shendelman founded Applied to develop cutting-edge treatments for rare diseases. Compl. ¶¶36–37. One of those treatments, govorestat, was developed to treat galactosemia, a rare, degenerative, and potentially life-threatening disease that predominantly affects children. *Id.* ¶41. Galactosemia renders patients unable to metabolize galactose, which can result in severe neurological complications. *Id.* ¶¶42–43.

During the putative Class Period, there were no FDA-approved treatments for galactosemia, and the only available intervention was dietary restriction of galactose, which provides only partial benefits and fails to prevent long-term neurological damage. *Id*. ¶43. Govorestat was developed to address this urgent unmet medical need by reducing levels of galactitol in both the blood and the brain, which would provide tangible clinical benefits, such as improved cognitive performance, enhanced motor skills, and better behavioral outcomes. *Id*. ¶44.

[2] This factual background is derived from the allegations in the Complaint and documents incorporated therein by reference, as required on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The description of Plaintiff's allegations is not an admission of the truth or completeness of any such allegation nor a concession of the actionability or materiality of any such allegation.

**B. Clinical Trials and NDA Submission for the Treatment of Galactosemia**

Applied began its first clinical trial for govorestat, the Adult Study, in June 2019. *Id.* ¶48. Applied then initiated the Pediatric Study in June 2020. *Id.* ¶54. The Pediatric Study was a two-part study to evaluate (i) the safety, pharmacokinetics, and reduction in the toxic biomarker, galactitol, and (ii) the impact on functional outcomes in children with galactosemia over time. *Id.* ¶55. Between March and June 2021, 19 test subjects in the Pediatric Study received only 80% of the intended dose. *Id.* ¶65. On June 17, 2021, Applied notified affected clinical sites of the Dosing Errors and distributed corrected doses by June 29, 2021. *Id.* ¶3. The Pediatric Study was unblinded in April 2023, and the results of the study were published on November 6, 2024. *Id.* ¶55–56; Ex. A.[3]

In December 2023, Applied submitted the NDA for govorestat for the treatment of galactosemia, which included results from both studies. Compl. ¶62. In February 2024, the FDA accepted the NDA and granted Priority Review status. *Id.* ¶¶85, 170. A Priority Review designation will "direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications." *Priority Review*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review.[4] The FDA also

[3] This Motion relies on sources attached as exhibits, which the Court may consider because they are "incorporated into the complaint by reference," are "legally required public disclosure documents filed with the SEC," or were "possessed by or known to the plaintiff and upon which it relied in bringing the suit." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007). These exhibits, attached to the accompanying Declaration of Jules H. Cantor, include copies of the Pediatric Study Results (Exhibit A), the November 27, 2024 Warning Letter (Exhibit B), and Dr. Shendelman's Form 4 filings dated March 18, 2024 (Exhibit C), June 10, 2024 (Exhibit D), and August 14, 2024 (Exhibit E).

[4] This Motion also draws on public statements of the FDA of which this Court may take judicial notice. *See, e.g., Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 60 (2d Cir. 2016) (taking judicial notice of FDA guidance on motion to dismiss "because the Guidance is publicly available and its accuracy cannot reasonably be questioned."); *Gordon v. Target Corp.*, 2022 WL 836773, at *2 (S.D.N.Y. Mar. 18, 2022) (taking judicial notice of two FDA

established a timeline for review of the NDA, assigning a PDUFA target action date[5] of August 28, 2024 and noting that it was planning to hold an advisory committee meeting to discuss the NDA. *Id.* ¶85. In March 2024, the FDA extended the PDUFA date to November 28, 2024. *Id.* ¶113.

**C. FDA Inspection and the Form 483**

On March 25, 2024, the FDA announced an inspection of one of Applied's clinical testing sites involved in the Pediatric Study. *Id.* ¶127. The Inspection was conducted as part of the FDA's Bioresearch Monitoring Program, which "includes inspections designed to evaluate the conduct of research and to help ensure that the rights, safety, and welfare of human subjects [are] protected." *Id.* ¶130.

The Inspection occurred between April 29 and May 3, 2024, at which time the FDA "requested access to verify electronic data collected and maintained in Q-Global®." *Id.* ¶130–134. Applied used Q-Global to capture certain electronic clinical outcome assessments. *Id.* ¶128. On March 27, 2024, Applied's third-party vendor deleted certain electronic data in Q-Global for subjects in the Pediatric Study. *Id.* ¶129. The FDA identified the Data Deletion and the Dosing Errors during the Inspection. *Id.* ¶11. Shortly thereafter, the FDA issued a Form 483[6] to Applied detailing findings from the Inspection. *Id.* ¶135. Applied's Form 483 did not identify the Dosing Errors among its observations. *See id.* ¶¶290; Ex. B at 5 ("We acknowledge that [the Dosing

webpages and observing that "[c]ourts may take judicial notice of public documents or . . . records of administrative bodies, such as government agencies like the FDA") (quotations and citations omitted).

[5] *See In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 35 n.2 (1st Cir. 2014) ("The PDUFA . . . requires the FDA to set a target date for approval of the application. This target date, however, is not a guarantee of approval nor is it binding on the FDA.").

[6] A Form 483 is issued "to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the [FD&C] Act and related Acts." Compl. ¶140. According to the FDA, a Form 483 "does not include observations of questionable or unknown significance at the time of the inspection." *Id.*

Errors] finding was not included on the Form FDA 483 you received, and therefore your written response does not address this finding."). The Form 483 did, however, include the Data Deletion. Compl. ¶138.

On May 9, 2024, Applied responded to the Form 483 and informed the FDA that source data for 11 test subjects, captured directly into Q-Global, could not be recovered in electronic format. *Id.* ¶141; Ex. B at 3. Applied further "indicated that steps have been taken to ensure the integrity of the remaining data," including the transfer of a copy of the electronic data set for backups and performance of "an assessment of systems to ensure that the third-party vendor did not have the capability to delete data from any other systems." Compl. ¶142; Ex. B at 3. Applied's May 9, 2024 written response also listed a series of planned preventive actions. *Id.*

**D. Advancement Through FDA Review**

Notwithstanding the concerns referenced in the Form 483, the FDA continued to advance the NDA through the approval process. The FDA held the Mid-Cycle Meeting in late Spring 2024, Compl. ¶230, and scheduled the Late-Cycle Meeting for September 18, 2024, *id.* ¶246. Additionally, throughout the summer and fall of 2024, the FDA and Applied corresponded about the NDA, including regarding the Data Deletion. *Id.* ¶290; Ex. B at 4.

On August 27, 2024, in response to an FDA Information Request, Applied explained that "an export of the . . . data from the backup Q-Global[] system is maintained with a third-party statistical consulting vendor; however, the data is no longer available in Q-Global[]." Compl. ¶218; Ex. B at 4. On September 11, 2024, in written response to the FDA's September 5, 2024 correspondence providing the Late-Cycle Meeting Background Package, Applied stated "that the third-party vendor deleted the data study from Q-Global system without consulting Applied" and that it was "able to recover data from the Q-Global system's backup,

except for the 11 tests." Applied also noted that "before the electronic data's deletion, item-level responses were captured in PDF and in paper copies of the score reports." Compl. ¶¶219–220; Ex. B at 4.

During the Late-Cycle Meeting, the FDA informed Applied that the Advisory Committee meeting, which was tentatively scheduled for October 9, 2024, was cancelled. Compl. ¶237. According to FDA guidance, an Advisory Committee meeting is typically held where the agency requires additional information. While "[o]ften, the NDA contains sufficient data for [the] FDA to determine the safety and effectiveness of a drug," "[s]ometimes . . . questions arise that require additional consideration." *Step 4 FDA Drug Review*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-4-fda-drug-review. In these cases, the FDA may organize an Advisory Committee "to get independent, expert advice and to permit the public to make comments." *Id.*

On November 27, 2024, just one day before the PDUFA date, Applied received a CRL. Compl. ¶272. That same day, Applied filed a Form 8-K stating that "[t]he CRL indicates that the FDA completed its review of the application and determined that it is unable to approve the NDA in its current form, citing deficiencies in the clinical application." *Id.* ¶275. On November 27, Applied also received the Warning Letter, which it disclosed in a Form 8-K filing on December 2, 2024. *Id.* ¶276, ¶288. The next day, the FDA published the Warning Letter. *Id.* ¶290.

**E. Dr. Shendelman's Stock Sales**

During the putative Class Period, on March 14, June 10, and August 12 through 14, 2024, Dr. Shendelman sold 1,157,382 of her shares of Applied common stock (the "March Sale," the "June Sale," and the "August Sale," and collectively, the "Sales"). *Id.* ¶303. The March Sale represented 3.76% of Dr. Shendelman's then-owned holdings, *id.* ¶107, the June Sale represented

0.76%, *id.* ¶181, and the August Sale represented 9.05%, *id.* ¶¶210–13. The March and June Sales were both made to "cover tax withholding obligations in connection with the vesting and settlement of compensatory Restricted Stock Units."[7] Exs. C–D. After the Sales, Dr. Shendelman retained 7,803,355 shares of Applied common stock. *Id.* ¶214.

**F. The Present Action**

On December 17, 2024, Adrian Alexandru filed a securities class action complaint, claiming that Defendants made false or misleading statements concerning the likelihood of FDA approval for the NDA. (ECF No. 1). On December 27, 2024 Mohammad Ali Ikram filed a similar action against Defendants. *See* Case No. 1:24-cv-09973 (ECF No. 1). On March 11, 2025, this Court consolidated the actions and appointed Martin Dietrich as Lead Plaintiff and Wolf Popper LLP as Lead Counsel to the proposed class. (ECF No. 59). On May 2, 2025, Plaintiff filed the Complaint. (ECF No. 72).

**ARGUMENT**

To state a claim under Section 10(b) of the Securities Exchange Act, a "plaintiff must establish that the defendant, in connection with the purchase or sale of securities, made a materially false statement or omitted a material fact, with scienter, and that the plaintiff's reliance on the defendant's action caused injury to the plaintiff." *ECA & Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co*., 553 F.3d 187, 197 (2d Cir. 2009).[8] The PSLRA imposes "[e]xacting pleading requirements" that "require[] plaintiffs to state with particularity both the facts constituting the alleged violation, and the facts evidencing scienter[.]" *Tellabs, Inc. v. Makor*

[7] The Court may take judicial notice of Dr. Shendelman's SEC Forms 4. *See, e.g.*, *In Re Keryx Biopharmaceuticals, Inc. Sec. Litig.*, 2014 WL 585658, at *13 & n. 9 (S.D.N.Y. Feb. 14, 2014) (finding "[t]he [c]ourt may take judicial notice of disclosures made in publicly available SEC documents" and considering similar "tax withholding" language in a Form 4).

[8] Unless otherwise noted, all internal citations and quotations are omitted and all emphasis is added.

*Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). Because Plaintiff fails to adequately allege scienter, the Complaint should be dismissed in its entirety. Moreover, and independently, certain alleged misstatements do not give rise to actionable claims for securities fraud.

## I. THE COMPLAINT FAILS TO PLEAD SCIENTER.

Under the PSLRA, Plaintiff must allege with particularity facts giving rise to a strong inference of scienter. The requisite state of mind is one "embracing intent to deceive, manipulate, or defraud." *Id.* at 319. To satisfy this requirement, Plaintiff must either (a) demonstrate "that defendants had the motive and opportunity to commit fraud," or (b) allege facts that constitute "strong circumstantial evidence of conscious misbehavior or recklessness." *ECA & Local,* 553 F.3d at 198. To plead recklessness, Plaintiff must establish that the alleged conduct was "highly unreasonable and . . . represent[ed] an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001). The scienter standard is "inherently comparative," and requires "more than [a] merely plausible or reasonable" inference. *Tellabs,* 551 U.S. at 314, 323. "A complaint will survive [a motion to dismiss] only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* at 324. If the inference of non-fraudulent intent is more compelling, Plaintiff's claim fails. *See In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 471–72 (S.D.N.Y. 2008).

Plaintiff's allegations of motive and recklessness fail to raise the strong inference required. Under controlling law, the trades identified by Plaintiff and the generic motive alleged are insufficient. And the facts alleged, including the FDA's decision to move the NDA through the review process, do not support an inference of recklessness—instead, the more compelling

inference is that Dr. Shendelman reasonably believed govorestat was moving closer to approval. Failing to predict the future is not securities fraud. The Section 10(b) claim should be dismissed.

**a. Plaintiff's Motive Allegations Fail as a Matter of Law.**

Plaintiff's allegations of motive—that Dr. Shendelman was motivated to have the NDA approved and keep the stock price high, Compl. ¶¶306–311, and profited by selling stock during the Class Period, *id.* ¶¶302–305—fail to raise a strong inference of scienter. To "raise a strong inference of scienter through 'motive and opportunity' to defraud, Plaintiff[] must allege that [the defendant] benefitted in some concrete and personal way from the purported fraud." *ECA & Local*, 553 F.3d at 198. The "bare invocation of magic words such as motive and opportunity" will not suffice. *In re PXRE Grp., Ltd., Sec. Litig.,* 600 F. Supp. 2d 510, 531 (S.D.N.Y. 2009).

Plaintiff fails to plausibly allege that Dr. Shendelman had a motive to commit securities fraud. The proportionate size of her trades—two of which were made to cover tax obligations—cannot support a strong inference of scienter, and the generic corporate objectives alleged are common among all executives and do not evince fraudulent intent under settled precedent.

***i. Dr. Shendelman's Stock Sales Do Not Support an Inference of Fraudulent Intent.***

"[T]he mere fact that insider stock sales occurred does not suffice to establish scienter." *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009). Rather, Plaintiff must establish that the alleged sales were "unusual" or "suspicious." *See Buhrke Fam. Revocable Tr. v. U.S. Bancorp*, 726 F. Supp. 3d 315, 358 (S.D.N.Y. 2024). Here, Plaintiff identifies three Sales during the Class Period, none of which, taken individually or viewed collectively, are sufficiently unusual or suspicious to give rise to a strong inference of scienter.

*First*, the March and June Sales provide no inference of scienter, as both were nondiscretionary sales to "cover tax withholding obligations in connection with the vesting and

settlement of compensatory Restricted Stock Units." Exs. C–D. Courts have repeatedly held that disposing of shares "to cover the tax withholding obligations due upon the vesting of shares of restricted stock . . . [is] not indicative of fraud." *In re Keryx Biopharmaceuticals, Inc., Sec. Litig.*, 2014 WL 585658, at *13 (S.D.N.Y. Feb 14, 2024); *see also N. Collier Fire Control & Rescue Dist. Firefighter Pension Plan v. MDC Partners, Inc.*, 2016 WL 5794774, at *20 (S.D.N.Y. Sept. 30, 2016) (same) (collecting cases). Indeed, the "disclosed nature" of such trades "suggests the [very] ***absence*** of [the] fraudulent motive" that Plaintiff must allege to survive a motion to dismiss. *MDC Partners*, 2016 WL 5794774, at *20.

*Second*, the Sales do not support an inference of scienter because they represent only a small percentage of Dr. Shendelman's total holdings, and it is settled law that "the inference of scienter is weakened" where sales are "only a small fraction of (the seller's) shares[.]" *In re Travelzoo Inc. Sec. Litig.*, 2013 WL 1287342, at *10 (S.D.N.Y. Mar. 29, 2013).

The March and June Sales—which, again, were made for tax purposes—represented less than 5% of Dr. Shendelman's total holdings on the date of each sale (3.76% and 0.76% respectively), Compl. ¶¶107, 181,[9] while the August Sale represented only 9.05% of her holdings.[10] *Id.* ¶¶210–13. These Sales do not constitute a suspicious benefit necessary for a strong inference of scienter. *See Acito v IMCERA Grp., Inc.*, 47 F.3d 47, 54 (2d Cir. 1995) (holding that sale of 11% of defendant's holdings was not sufficiently unusual to satisfy burden to plead scienter);[11] *see also In re Axis Cap. Holdings Ltd., Sec. Litig.*, 456 F. Supp. 2d 576, 595 (S.D.N.Y.

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[9] *See also* Exs. C–D.

[10] *See also* Ex. E.

[11] Though decided prior to the enactment of the PSLRA, *Acito* continues to be relied on by this Circuit. *See, e.g.*, *Saraf v. Ebix, Inc.*, 2024 WL 1298246, at *3 (2d Cir. Mar. 27, 2024) (citing *Acito* for proposition that motive to maintain a high stock price to increase executive compensation does not give rise to a strong inference of scienter).

2006) ("[C]ourts of this district have held that 'insider sales that represent less than ten percent of that insider's holdings are insufficiently "unusual" to permit an inference of scienter.'").

Plaintiff alleges that, collectively, the Sales "represented 14.32% of [Dr. Shendelman's] holdings of 8,080,945 shares prior to the start of the Class Period," Compl. ¶303, but even if the March and June Sales were relevant, this percentage is far too low to establish a strong inference of scienter. *See In re eSpeed, Inc. Secs. Litig.*, 457 F. Supp. 2d 266, 291 (S.D.N.Y. 2006) (holding that Second Circuit guidance "would clearly lead to a finding that" sales of 17.4% and 10.9% of defendants' holdings "are *de minimis*") (citing *Acito*, 47 F.3d at 54); *see also Travelzoo*, 2013 WL 1287342, at *10 (finding that an individual defendant's sale of 22% of his stockholdings for $186 million was not unusual because he still retained 78% of his total stockholdings); *In re Keyspan Corp. Sec. Litig.*, 383 F. Supp. 2d 358, 382–83 (E.D.N.Y. 2003) (finding no inference of scienter where "the individual defendants sold less than 20% of their available holdings" and noting that "[c]ourts have found no inference of scienter in cases involving even greater percentages of sales").

Further, the sheer size of Dr. Shendelman's holdings after the Sales is entirely inconsistent with fraudulent intent. As Plaintiff acknowledges, Dr. Shendelman owned or controlled ***7,803,355*** shares of Applied common stock following the Sales. Compl. ¶214. It is implausible that Dr. Shendelman allegedly knew that govorestat would not be approved, yet continued to hold 90% of her stock after the August Sale. *See Frankfurt-Tr. Inv. Luxemburg AG v. United Techs. Corp.*, 336 F. Supp. 3d 196, 218 (S.D.N.Y. 2018) (finding no motive where defendant "still retained millions worth of stock options after his sale"). Plaintiff's allegations do not support an inference of scienter.

**ii. *The Motivation of Corporate Actors to Keep the Stock Price High is Not Indicative of Scienter.***

Plaintiff further alleges that "Dr. Shendelman Was Motivated to Have the NDA Approved and Keep the Stock Price High." Compl. ¶¶306–311. Because it is reasonable—indeed, expected—that executives want to see their companies succeed, such generic and conclusory allegations do not give rise to the strong inference of scienter required to carry Plaintiff's burden under the PSLRA. Accordingly, courts have declined to infer scienter from general motives such as "(1) the desire for the corporation to appear profitable and (2) the desire to keep stock prices high to increase officer compensation." *Kalnit*, 264 F.3d at 139; *see also Acito*, 47 F.3d at 54 ("Plaintiff's allegation that defendants were motivated to defraud the public because an inflated stock price would increase their compensation is without merit.").[12] Because Dr. Shendelman's desire for the NDA to be approved—that is, for Applied to succeed—is a "[m]otive[] that [is] common to most corporate officers," it likewise cannot establish scienter. *ECA & Local*, 553 F.3d at 198.

**b. Plaintiff Fails to Allege Circumstantial Evidence of Conscious Misbehavior or Recklessness.**

Failing to allege motive, Plaintiff's Section 10(b) claim survives only if it alleges specific facts constituting "'strong circumstantial evidence' of . . . 'conscious misbehavior or recklessness.'" *Kalnit*, 264 F.3d at 142. Recklessness is conduct that is "highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it[.]" *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) (emphasis

[12] Plaintiff's allegations that Dr. Shendelman was motivated to inflate Applied's stock price in September and October 2024 to reach incentive compensation goals, Compl. ¶¶309–311, are undercut by the longstanding principle that "[i]ncentive compensation can hardly be the basis on which an allegation of fraud is predicated." *Acito*, 47 F. 3d at 54; *Kalnit*, 264 F.3d at 139–141 (collecting examples of alleged motive related to compensation and corporate performance insufficient for scienter).

omitted). Without any well-pleaded allegations of motive, "the strength of [Plaintiff's] circumstantial allegations must be correspondingly greater." *Kalnit*, 264 F.3d at 142. Plaintiff has not met this high burden.

Plaintiff alleges that Dr. Shendelman was aware of, or severely reckless in not knowing, that the Data Deletion and the Dosing Error constituted a material risk that the FDA would reject the NDA. Compl. ¶¶148–208. This theory is undermined by Plaintiff's own allegations, *e.g.*, *id.* ¶219, which show that, despite the FDA's awareness of the Data Deletion and the Dosing Error, it did not immediately issue a CRL or inform Applied that approval was implausible, much less impossible. To the contrary, it continued to advance govorestat through the review process. Plaintiff's various remaining allegations—that Dr. Shendelman was a "key employee," govorestat was Applied's "core operation", and Dr. Shendelman put her knowledge on the subject "at issue"—endeavor to circumstantially show scienter in ways that have been rejected by Second Circuit courts and cannot carry Plaintiff's heightened burden under the PSLRA. Compl. ¶¶312–28. *See infra* Sections II(b)(ii)-(iv).

**i. *Dr. Shendelman's Awareness of the Data Deletion and the Dosing Errors Does Not Support Scienter.***

Plaintiff alleges that Dr. Shendelman's optimistic statements about the NDA's approval prospects were reckless considering her knowledge of the Data Deletion and the Dosing Errors. Compl. ¶¶148–208. This hindsight theory fails for several reasons.

*First*, Dr. Shendelman's awareness of potential regulatory hurdles alone does not support an inference of scienter. "In the context of the development and approval process for a new drug," there is scienter only "if the management ***knows that certain facts will necessarily prevent the regulatory approval***[.]" *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 579 (S.D.N.Y. 2016). "If, on the other hand, the management of the company releases positive reports about the drug to

the public along the way ***which the management honestly believes to be true***, and where there is no reckless disregard for the truth, then that is not securities fraud." *Id.* Plaintiff fails to allege any particularized facts indicating that Dr. Shendelman ***knew*** the Data Deletion or Dosing Errors would ***necessarily prevent*** approval.

*In re Sanofi Securities Litigation* is instructive. 87 F. Supp. 3d 510 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi,* 816 F.3d 199 (2d Cir. 2016). There, a pharmaceutical company sought approval of a drug utilizing a single-blind study. *Id.* at 519. Numerous times throughout the review process, the FDA "expressed concerns" about the design of the study and even advised the company that the clinical trials would "'not provide substantial support' for a license application." *Id.* Nevertheless, the FDA continued to advance the drug through its review stages. *Id.* The company did not publicly disclose the FDA's stated concerns about the study design and "continued to make optimistic statements about [the drug's] prospects." *Id.* at 522. Thereafter, the FDA rejected the application for the drug. *Id.* at 523. The company's shareholders filed a Section 10(b) claim, arguing that "defendants knew about the design shortcomings in the . . . clinical trials. . . yet failed to disclose that interim feedback, and were aware or recklessly failed to appreciate that the absence of such a disclosure made their optimistic projections about FDA approval false and misleading." *Id.* at 534. In dismissing the plaintiff's claims, the court declined to draw an inference of scienter, because, "in expressing misgivings about a single-blind methodology, the FDA did not state that it would ***refuse*** to approve [the drug] were this methodology used." *Id.* at 533. Rather, "a series of actions by the FDA . . . communicated that . . . agency approval ***was*** possible." *Id.* (emphasis in original).

Here, Plaintiff fails to allege that Dr. Shendelman did not genuinely believe the NDA could be approved, let alone that she knew Applied would receive a CRL. And the FDA's statements

and actions allegedly known to Dr. Shendelman "were by no means inconsistent with [her] stated optimism." *Id.* at 534.

To the contrary, Applied's interactions with the FDA supported Dr. Shendelman's reasonable belief that approval was possible. Despite its awareness of the Data Deletion and Dosing Errors, the FDA continued to advance govorestat through the review stages. After identifying the Data Deletion and Dosing Errors during the Inspection, Compl. ¶76, the FDA proceeded with the Mid-Cycle and Late-Cycle Meetings, *id.* ¶¶230, 237. The FDA also continued to correspond with Applied regarding the Data Deletion through summer and fall of 2024. *Id.* ¶¶246, 290.

And the Warning Letter acknowledges that the Form 483 issued after the FDA's inspection ***did not even mention the Dosing Errors***. Compl. ¶290. As Plaintiff notes, the purpose of a Form 483 is to "notif[y] the company's management of objectionable conditions." *Id.* ¶140. A Form 483 does not include observations if they are "of questionable or unknown significance at the time of the inspection." *Id.* The reasonable inference, therefore, to be drawn from the fact that the Dosing Errors were not identified in the Form 483 was that the FDA considered them to be "of questionable or unknown significance." *Id.* Moreover, the Pediatric Study Results indicate that "several of the key secondary endpoints were statistically significant and demonstrated substantial clinical benefit of govorestat at 18 months," *see* Ex. A at 7, despite some participants receiving a lower dose than intended. It is unreasonable to believe that if patients had received the intended dose, the results would be ***less*** statistically significant. These facts weigh against Plaintiff's assertion that Dr. Shendelman should have known that the Dosing Errors would result in a CRL and Warning Letter; they certainly do not support an inference of recklessness.

Further, the mere fact that the FDA provided interim feedback to Applied during the review process does not support a strong inference of scienter. In *In re Alkermes*, the court found a lack of scienter where the defendant was similarly aware of FDA concerns but "the FDA nonetheless permitted the drug to proceed through various stages of approval prior to its ultimate denial of the application." *In re Alkermes Pub. Ltd. Co. Sec. Litig.*, 523 F. Supp. 3d 283, 295 (E.D.N.Y. 2021). The court found that the FDA's communications to the company expressing its concerns did not reveal information conveying that "FDA approval of the [drug] was not possible or even unlikely." *Id.* at 295; *see also In re Sanofi*, 87 F. Supp. 3d at 545 ("[T]he significance of [the FDA's interim] feedback became apparent only after the FDA had released. . . its decision not to approve [the drug]"). Here, too, there was no indication that approval was unlikely. To the contrary, "implicit in the ongoing dialogue between the FDA and [Applied] was a collective expectation that the process was an iterative one and that [Applied] would continue to respond to feedback in its continued effort to seek approval of [govorestat]." *In re Alkermes*, 523 F. Supp. 3d at 294.

The fact that Applied received a Form 483 from the FDA also does not support a strong inference of scienter. In *In re Checkpoint Therapeutics Sec. Litig.*, 2025 WL 1434400, at *23 (S.D.N.Y. May. 19, 2025), the court rejected the theory that defendants—by allegedly concealing a manufacturing third-party's receipt of Forms 483—"knowingly misled the market about [the company's] prospects for receiving FDA approval[.]" The court found that the "fraud scheme that [plaintiff] envisions within [the company]—to conceal the fact that the Form 483 presented an insurmountable obstacle, as opposed to a readily clearable regulatory hurdle—is not coherent." *Id.* at *24. While the plaintiff in *In re Checkpoint* failed to allege defendants knew of the Forms 483, the court observed that "even assuming . . . it were well-pled that defendants knew[,]" the Forms 483 were "'merely observational in nature, and d[id] not represent the FDA's final word.'"

*Id.* at *17 (alterations in original). "The 'advisory language' of a Form 483 indicates that 'it lists only inspectional observations and do[es] not represent a final agency determination regarding [] compliance.'" *Id.* (alterations in original).

Like the CEO defendant in *In re Checkpoint*, Dr. Shendelman "had sound reasons not to treat the Form 483 as more than a navigable speed bump." *Id.* at *27. The facts that the Form 483 was "observational in nature" and "did not overtly threaten [the drug's] PDUFA goal date" similarly undermine an inference of scienter. *See id.* Plaintiff's "speculative competing inference" is far less compelling than the inference that Dr. Shendelman, "who did not have an affirmative duty to mention the Form 483, did not do so because [she] believed that [govorestat] remained on track for timely FDA approval." *Id.*

The fact that govorestat continued to advance through the review process also cuts against an inference of recklessness. The FDA could have issued a CRL at any time, including at the time of the Inspection, the Mid-Cycle Meeting, or the Late-Cycle Meeting.[13] As the review process proceeded without a CRL, Dr. Shendelman had reason to honestly believe that the NDA might be approved. Put differently, the "FDA's negative feedback was muted by a series of encouraging regulatory decisions" that allowed the NDA to proceed through the approval process prior to ultimate disapproval. *In re Sanofi*, 87 F. Supp. 3d at 545. Plaintiff fails to allege that the FDA ever communicated that approval of the NDA was impossible, or even unlikely. These facts cannot support an inference of recklessness.

[13] *See*, e.g., 21 CFR § 314.110 (2024) (if the FDA determines that the submitted data is "inadequate to support approval," the FDA may "issue a complete response letter without first conducting required inspections and/or reviewing proposed product labeling").

*Second*, Plaintiff's theory relies on the premise that, because govorestat was ultimately not approved, earlier optimistic statements must have been at least reckless. But this is exactly the type of impermissible hindsight pleading that has been repeatedly rejected by courts in this Circuit.

Plaintiff cannot allege "fraud by hindsight" to establish recklessness. Courts have held that "[m]ere allegations that defendants should have anticipated future events and made certain disclosures earlier than they actually did do not suffice to make out a claim of securities fraud." *Gissin v. Endres*, 739 F. Supp. 2d 488, 501 (S.D.N.Y. 2010); *see also City of Sterling Heights Police & Fire Ret. Sys. v. Abbey Nat'l., PLC*, 423 F. Supp. 2d 348, 357 (S.D.N.Y. 2006). That the NDA was later denied does not imply that Dr. Shendelman's statements made during the regulatory process were knowingly false or reckless. After all, "[c]orporate officials need not be clairvoyant[.]" *City of Sterling Heights Police & Fire Ret. Sys. v. Vodafone Grp. Pub. Ltd. Co.*, 655 F. Supp. 2d 262, 268 (S.D.N.Y. 2009).

Dr. Shendelman's alleged "optimism," *e.g.*, Compl. ¶294, also does not support an inference of recklessness. A corporate officer's "misguided optimism is not a cause of action, and does not support an inference of fraud." *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994). And even when "optimism about a prosperous future turn[s] out to be unwarranted," that "is not circumstantial evidence of conscious fraudulent behavior or recklessness," *In re HEXO Corp. Sec. Litig.*, 524 F. Supp. 3d 283, 314 (S.D.N.Y. 2021), because company management is "not required to take a gloomy, fearful or defeatist view of the future," *Shields*, 25 F.3d at 1129. In other words, optimism is not the same as recklessness, because the law does not require executives to expect and foresee the worst.

*Finally*, Plaintiff's allegation that Dr. Shendelman was reckless in not knowing that "omissions and errors in the NDA were a significant and material negative factor for approval of

the NDA, and [posed] a serious risk that the FDA would reject [the] NDA" is simply a repackaged argument that Dr. Shendelman "ought to have known" better. Compl. ¶316. "An allegation that a defendant merely ought to have known is not sufficient to allege recklessness." *In re Lululemon Litig.*, 14 F. Supp. 3d 553, 574 (S.D.N.Y. 2014); *see also In re MELA Sciences, Inc. Sec. Litig.*, 2012 WL 4466604, at *9 (S.D.N.Y. Sept. 19, 2012) (finding plaintiffs' claim that defendants "should have known approval would be delayed because of the trial's flaws" to be "insufficient to adequately plead strong circumstantial evidence showing recklessness"). Taken together, Plaintiff's allegations are insufficient to establish recklessness and cannot support an inference of scienter.

**ii. *Allegations That Dr. Shendelman Was a Key Employee and an Author of the Pediatric Study Are Insufficient.***

Plaintiff's allegations concerning Dr. Shendelman's role as a "key employee" of Applied and her involvement in the Pediatric and Adult Studies also do not raise any inference of scienter. Compl. ¶¶312–17. Alleging that Dr. Shendelman was a "key employee" and therefore must have known that the alleged misstatements were false or misleading is conclusory and courts have repeatedly rejected such futile attempts to establish scienter. *See, e.g., Foley v. Transocean Ltd.*, 861 F. Supp. 2d 197, 212 (S.D.N.Y. 2012) ("Scienter cannot be inferred solely from the fact that, due to the defendants' . . . executive managerial position, they had access to . . . adverse information."). The only other allegation Plaintiff makes in support of this "key-employee" theory is that, because Dr. Shendelman was "critically involved in the Pediatric Study," she was aware, or severely reckless in not being aware, that the Data Deletion and the Dosing Errors constituted a material risk that the FDA would reject the NDA. Compl. ¶316. This is merely another repackaged version of Plaintiff's fraud-by-hindsight argument, *id.* ¶¶148–208, and fails for the same reasons discussed above: Dr. Shendelman's awareness of the Data Deletion and Dosing Errors do not

support an inference of scienter because the FDA's actions indicated approval *was* still possible. *See supra* Section I(b)(i).

**iii. *The Core Operations Doctrine Cannot Independently Establish Scienter.***

Next, Plaintiff attempts to establish an inference of scienter by invoking the core operations doctrine as it relates to the approval of the NDA and the subsequent commercialization of govorestat. Compl. ¶¶318–26. The core operations doctrine allows a court to "infer that a company and its senior executives have knowledge of information concerning the core operations of a business, such as events affecting a significant source of revenue." *In re Spero Therapeutics, Inc., Secs. Litig.*, 2024 WL 4593422, at *8 (E.D.N.Y. Oct. 28, 2024). The Second Circuit, however, "has not expressly determined if the core operations doctrine remains applicable to proving scienter after the enactment of the PSLRA." *In re Paysafe Sec. Litig.*, 2025 WL 1003322, at *30 (S.D.N.Y. Mar. 31, 2025*)*; *see also Frederick v. Mechel OAO*, 475 F. App'x 353, 356 (2d Cir. 2012) ("[W]e have not yet expressly addressed whether, and in what form, the 'core operations' doctrine survives as a viable theory of scienter."). But even assuming the theory is viable in some instances, recent decisions in this Circuit indicate that a "core operations" theory provides—at most—"supplementary but not independently sufficient means to plead scienter." *Denny v. Canaan Inc.*, 2023 WL 2647855, at *14 (S.D.N.Y. Mar. 27 2023); *see also Glantz v. James River Group Holdings, Ltd.*, 2025 WL 278440, at *8 (S.D.N.Y. Jan. 23, 2025). Because Plaintiff's other allegations of scienter are insufficient, there is nothing for the core operations theory to "supplement," so it cannot save Plaintiff's deficient claims.

**iv. *The Fact That Dr. Shendelman Spoke Regularly About the NDA Does Not Establish Scienter.***

Finally, Plaintiff alleges that Dr. Shendelman spoke regularly and in detail about the NDA, thereby putting her knowledge on the subject at issue. Compl. ¶¶327–28. But courts have rejected

this premise as circular and insufficient. For instance, in *In re Bristol-Myers Squibb*, plaintiffs argued that the fact that the company's "'top management repeatedly made false or misleading statements' is . . . probative of scienter." *In re Bristol-Myers Squibb Co. CVR Sec. Litig.*, 658 F. Supp. 3d 220, 233 n.6 (S.D.N.Y. 2023). The court rejected this argument, finding that it is "circular" and "without merit." *Id.* ("[A]lleging that [statements] were incomplete or that they omitted material information[] is not enough to plead scienter based on conscious misbehavior or recklessness."); *see also In re Bristol-Myers Squibb Co. CVR Sec. Litig.*, 2024 WL 873436, at *4 n.2 (S.D.N.Y. Feb. 29, 2024) (finding no inference of scienter where company "executives regularly spoke in detail about the state of the . . . approval process").

## II. THE COMPLAINT ALLEGES NUMEROUS INACTIONABLE MISSTATEMENTS

Moreover, many of Plaintiff's alleged misstatements are independently inactionable.[14] First, Dr. Shendelman's expressions of optimism about the NDA's approval prospects are statements of opinion and inactionable puffery. *See Gillis*, 197 F. Supp. 3d at 585 n.15 (finding statements regarding future FDA approval to be "inactionable 'expression[s] of puffery and corporate optimism'"). Second, Plaintiff fails to allege that Dr. Shendelman's statements about the progress of the FDA's review were anything but truthful statements of fact. *See In re MELA Sciences*, 2012 WL 4466604, at *12 (holding that defendant's statements that the FDA granted expedited review were "accurate statements of fact" and therefore inactionable).

[14] Attached as Appendix A is a compilation of the alleged misstatements relevant to this Section. Dr. Shendelman's focus on these alleged misstatements should not be construed as a concession as to the alleged misstatement's actionability, and Dr. Shendelman reserves all rights to challenge the actionability of any alleged misstatement should this matter proceed past the pleadings stage.

**a. Statements Expressing Optimism for NDA Approval Were Immaterial.**

**i. *Expressions of Confidence in NDA Approval***

The Complaint identifies as alleged misstatements a variety of statements by Dr. Shendelman expressing confidence in the approval of the NDA, such as "we remain confident in the potential for govorestat approval," "things are going very well," and FDA interactions are "on track." *See* App'x A FS12, App'x A FS21, App'x A FS23. But such statements are nothing more than the "ordinary expressions of corporate optimism" that courts hold inactionable, and accordingly cannot support a Section 10(b) claim. *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 557 (S.D.N.Y. 2004); *see also In re EDAP TMS S.A. Sec. Litig.*, 2015 WL 5326166, at *12 (S.D.N.Y. Sept. 14, 2015) (dismissing Section 10(b) claims based on statements that FDA review process was "on track" because, "insofar as these statements place a positive spin on developments in the . . . process, they constitute inactionable puffery and corporate optimism").

Indeed, the majority of the alleged misstatements in the Complaint are substantially similar to those rejected in *In re Bristol-Myers*—specifically, statements regarding (i) the opportunity to bring the drug to and potential to help patients,[15] (ii) the potential commercial launch of the drug,[16] and (iii) "confidence" in FDA approval[17]—each of which is inactionable. 312 F. Supp. 2d at 557–558. Analyzing each category, the *In re Bristol-Myers* court concluded such statements to be "plainly opinions, not guarantees" of FDA approval. *Id.* Indeed, courts repeatedly hold that

[15] *See, e.g.*, App'x A FS33 ("[W]e look forward to ***potentially making this drug available to patients*** later this year in the U.S., and in early 2025 in the EU."); App'x A FS61 ("As we approach the final stages of the NDA review process for Classic Galactosemia in parallel with a near-term NDA submission for SORD Deficiency, we remain confident in the promise of govorestat and its ability to address the underlying mechanisms of both diseases. We look forward to the ***opportunity to bring govorestat to patients*** in 2025.").

[16] *See, e.g.*, App'x A FS32 ("With potential approvals on the horizon, we are ***continuing to prepare for commercial launch of govorestat*** and have built a strong commercial and operational team.").

[17] *See, e.g.*, App'x A FS28 ("And with Govorestat having a very positive safety profile, we think the risks are very low. And then we look to the benefit. And I think the benefit that we have demonstrated in our clinical studies is very clear and substantial, and clinically meaningful to parents and to patients. And so, ***we're very confident in the process*** and we're very hopeful that this will be the first drug approved for Galactosemia later this year.").

similar statements expressing confidence in FDA approval are insufficient to form the basis for a Section 10(b) claim. In *Fort Worth*, the court found that "mere[] expressions of 'hope' that the FDA would approve [the drug]" were "soft" and "immaterial on their face as a matter of law." *Fort Worth Emps.' Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 230 (S.D.N.Y. 2009); *see also Gillis*, 197 F. Supp. 3d at 589 (holding that defendant's statements that it was "encouraged" by the FDA's feedback and "confident" that a drug would receive FDA approval were each inactionable opinions). The Court should likewise do so here.

The fact that the Form 483 was not disclosed does not change the analysis. The Complaint does not articulate why Dr. Shendelman should have reasonably expected a denial of govorestat based on receipt of the Form 483. After all, a Form 483 "presents as a formidable problem" only "in hindsight[,] with awareness that the FDA ultimately did not approve [a drug] by its . . . PDUFA . . . date." *In re Checkpoint*, 2025 WL 1434400, at *17.

**ii. *Statements Referencing Applied's Regulatory Progress***

Dr. Shendelman's statements referencing the regulatory progress achieved by Applied are likewise inactionable. In *Gillis*, the court found an officer's characterization of a company's "initiation and filing of the NDA as 'milestones' that reflected the 'significant progress' the company was making toward FDA approval" to be an "inactionable expression of puffery and corporate optimism." 197 F. Supp. 3d at 585 n.15. *Gillis* reasoned that similar statements are "too 'broad and nebulous as to not provide any specific or concrete guarantee on which a reasonable investor could have relied.'" *Id.* The Court should apply the same reasoning here to conclude that Applied's statements about making "significant clinical and regulatory progress" and achieving "key milestones for [its] rare disease pipeline," App'x A FS7, are likewise inactionable and cannot form the basis for Plaintiff's Section 10(b) claim. *See Schaeffer v. Nabriva Therapeutics PLC*, 2020 WL 7701463, at *9 (S.D.N.Y. Apr. 28, 2020) (statements "[d]escribing the NDA submission

as 'another major milestone' . . . are classic examples of puffery"); *In re EDAP*, 2015 WL 5326166, at *4, 10 (statement that FDA's acceptance of a company's application was a "major milestone" was puffery).

These statements are inherently subjective, made in the context of a regulatory process known to be lengthy and uncertain,[18] and incapable of being proven true or false at the time they were made. *See In re Bristol-Myers*, 312 F. Supp. 2d at 562 (noting there is an "inherent" amount of "uncertainty . . . in any application for FDA approval"). Accordingly, each is inactionable.

**b. Statements Related to the Late Stage of the NDA Review Process and the PDUFA Date Are Not False.**

Plaintiff also identifies as misstatements certain statements describing the status of the FDA's review. But the Complaint does not allege that these statements were false, and the statements are therefore inactionable. *See id.* at 557 ("It is well settled that a complaint alleging violations of the securities laws may not rely upon statements that are true.").

In *Fort Worth*, the court found alleged misstatements that "the FDA accepted [an NDA] . . . for review" and that "the FDA is expected to respond to [the] NDA" by a certain date inactionable because they "merely recite[] . . . historical fact[s] . . . not alleged to be false." 615 F. Supp. 2d at 230. Just as in *Fort Worth*, certain alleged misstatements identified in the Complaint "are in no way misleading" and are therefore inactionable. *In re MELA Sciences,* 2012 WL 4466604, at *12; *see also Gillis*, 197 F. Supp. 3d at 586 (finding certain alleged misstatements to be "accurate statements of objective historical facts" and "not at all misleading").

[18] The timeline for the PDUFA process alone takes "generally ten months for most [NDAs] and six months for those with priority review." Compl. ¶86.

For example, statements that the PDUFA date was rescheduled for November 28, 2024,[19] and that the NDA was in "late stage" review,[20] are simply recitations of fact. Nowhere does the Complaint allege that the PDUFA date was not, in fact, rescheduled, or that it was rescheduled for a different date than November 28, 2024. And it was true that the NDA was in the late stage of FDA review. Compl. ¶219 ("On September 5, 2024, the FDA sent Applied correspondence providing the ***Late Cycle Meeting*** Background Package . . .").

Plaintiff alleges that the omission of the Data Deletion and Dosing Errors made these statements misleading, because "these undisclosed facts were negative material factors and a significant risk that the FDA would not approve the NDA." Compl. ¶268. This is the same fraud-by-hindsight approach that has been firmly rejected by this Circuit and can no more render the statements false than it can create an inference of scienter. *Shields*, 25 F.3d at 1129 ("[Plaintiff's] technique is sufficient to allege that the defendants were wrong; but . . . [w]e have rejected the legitimacy of 'alleging fraud by hindsight.'"). It is simply not enough to allege that a statement was "not borne out by subsequent events." *See Bazzelle v. Novocure Ltd.*, 2025 WL 843668, at *9 (S.D.N.Y. Mar. 18, 2025). Because Plaintiff "relies on the ultimate outcome[,]"—that is, the failure of the Company to receive FDA approval—"to support his assertion that the statements were false and misleading, he is engaged in classic 'fraud by hindsight' pleading." *Diabat v. Credit Suisse Grp. AG*, 2024 WL 4252502, at *19 (S.D.N.Y. Sep. 19, 2024). This effort fails.

[19] *See, e.g.,* App'x A FS64 ("For Galactosemia, we're under review at the FDA with a ***PDUFA date of November 28th*** this month . . .").

[20] *See, e.g.*, App'x A FS67 ("So to sum up, ***govorestat is in late stage review*** and development for two rare diseases, Galactosemia and SORD Deficiency.").

Plaintiff has failed to allege that the statements related to the late stage of the review process and the PDUFA date are false. Therefore, these statements are inactionable, and should be dismissed.

## III. THE SECTION 20(A) CLAIMS SHOULD BE DISMISSED.

Because Plaintiff fails to state a violation of Section 10(b), the Section 20(a) claim against Dr. Shendelman likewise fail. *See ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007) (holding that, because plaintiff "fail[ed] to allege any primary violation" under Section 10(b), it could not "establish control person liability" under Section 20(a)).

## CONCLUSION

For the foregoing adequate and independent reasons, the Complaint should be dismissed in its entirety.

Dated: May 23, 2025

Respectfully submitted,

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**LOCAL RULE 7.1(c) CERTIFICATION**

I hereby certify that the foregoing Memorandum of Law complies with the word-count limitations as set forth in Local Rule 7.1(c). The foregoing Memorandum contains 8,741 words, exclusive of the caption, any index, table of contents, table of authorities, signature blocks, or any required certificates, but does include material contained in footnotes, according to the word processing software used to prepare it.

Dated: New York, New York
May 23, 2025

Respectfully submitted,

*Rachel M. Fritzler*

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